AMENDED IN ASSEMBLY MAY 5, 2009

AMENDED IN ASSEMBLY APRIL 15, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1458

Introduced by Assembly Member Davis

February 27, 2009

An act to add Article 7 (commencing with Section 111657.10) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1458, as amended, Davis. Drugs: adverse effects: reporting.

Existing law establishes various programs for the prevention of disease and the promotion of health to be administered by the State Department of Public Health. Existing law also contains provisions for the licensing and regulation of health professionals. Existing law requires the department to regulate the manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.

This bill would require health professionals, *as defined,* to report serious adverse drug events, *as defined,* to the federal Food and Drug Administration and would exempt violations from related criminal provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657.10) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

~~111657.10. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist,~~

111657.10. (a) For purposes of this article:

(1) "Licensed health professional" only includes a physician and surgeon, dentist, pharmacist, registered nurse, nurse practitioner, and physician's assistant.

(2) "Serious adverse drug events" shall include adverse health outcomes involving patients that result in death, life-threatening

conditions, hospitalization, disability, or congenital anomaly, or that require intervention to prevent permanent impairment or damage. A serious drug event shall not include medication errors, as described in Section 1279.1.

(b) A licensed health professional shall report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA).

~~(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or that require intervention to prevent permanent impairment or damage.~~

(c) Any health professional that is required to report an adverse drug event pursuant to this section shall use the FDA 3500 Voluntary form developed by the FDA for MedWatch.

111657.15. A licensed health professional ~~that~~ *who* violates any provision of this article shall not be subject to the penalties and remedies outlined in Chapter 8 (commencing with Section 111825). Nothing in this section affects otherwise existing duties, rights, or remedies under the law.

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